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10/508,893

01/26/2005

Scott K. Thompson

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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

11/13/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary

Application No.

10/508,893

Applicant(s)

THOMPSON ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25-47 and 56-58 is/are pending in the application.
- 4a) Of the above claim(s) 25-47 and 56-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/04, 5/05, 5/07</u> . | 6) <input type="checkbox"/> Other: _____ |

The Status of Claims

Claims 1-23, 25-47, and 56-58 are pending.

Claims 1-23 are rejected.

Claims 25-47, and 56-58 are withdrawn from consideration.

DETAILED ACTION

1. Claims 1-23 are under consideration in this Office Action.

Priority

2. It is noted that this application is a division of 10/243,731 filed on 09/16/2002, which is a continuation of 09/489,157 filed on 01/21/2000(US 6,465,513), which claims benefit of 60/116,735 filed on 01/22/1999, and claims benefit of 60/117,743 filed on 01/29/1999 .

Drawings

3. None.

Claim Objections

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Claims 1,13-14,19,22 are objected to because of the following informalities:

In Claims 1,13-14,19,22, the terms and the phrases " Het", " a 4-7 memebered heterocyclic ring which optionally contains one or more additional heteroatoms selected from N, O and S ", " pyridyl group ", " 6-methyl-pyridin-2-yl",

"

(R)-2-(3-{3-[[6-methyl-pyridin-2-ylmethyl](2,2-diphenylethyl)amino]-2 methyl-propoxy}-phenyl)acetic acid;

" are recited. These terms are related to the non-selected Group II.

Therefore, those chemical formulas containing these terms should be removed from the claims according to the proper restriction requirement.

Restriction /Election

Applicant's election with traverse of Group I (claims 1-23) : non-hetero compounds containing various aliphatic and cyclic compounds on 9/11/07 is acknowledged.

Groups II-IV are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group II-IV, there being no allowable generic or linking claims.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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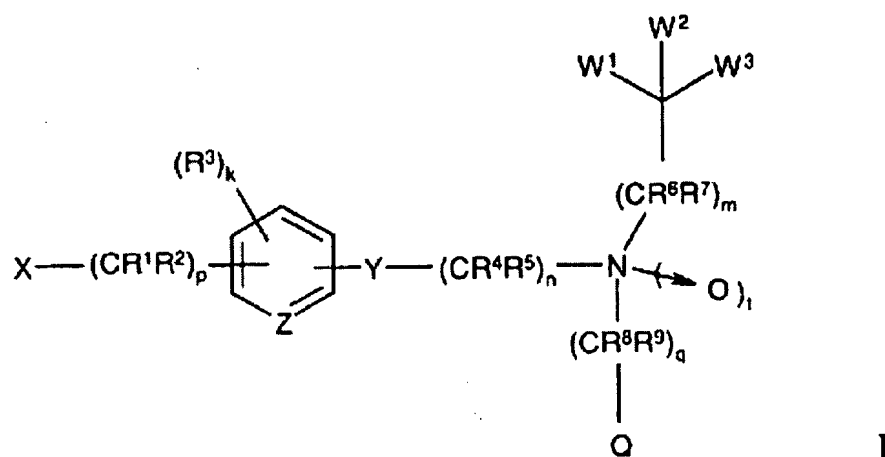
Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49-57, 59-67, 71 of copending Application No. 10/508,894. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are in a

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relationship between the species and the genus; mostly the scope of the current invention and that of the copending Application No. 10/508,894 are inclusive of each other in view of comparing their variables in their respective claims ; they are overlapped with each other.

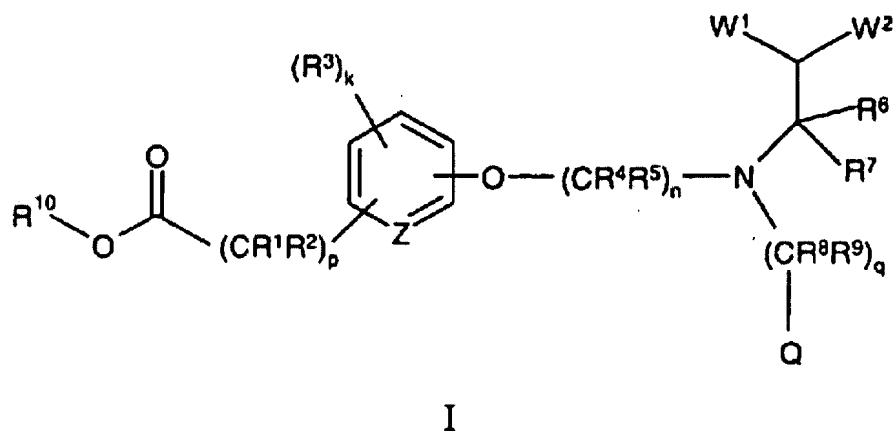
The claim 49 of the copending Application No. 10/508,894 describes below:

49. (Currently amended): A compound of Formula I:



, whereas the claim 1 of the current invention is as follows:

1. (Original): A compound of Formula I:



However, the differences between the instant invention and the copending Application No. 10/508,894 are as followed: there is no variable W^3 and no

attachment of the " $\text{---} \text{O} \text{---}$ " to the nitrogen as the branch.

Even so, regarding the absence of variable W^3 , the claimed compound has a hydrogen, which is the same group as the one of the variables of W^3 and also for the absence of attachment of the " $\text{---} \text{O} \text{---}$ " to the nitrogen atom, the formula I for the co-pending application has shown that the variable t can be zero.

The rest of claims in copending Application are very similar to those in the instant invention. They are in a relationship between the species and the genus; mostly the scope of the current invention and that of the copending Application No. 10/508,894 are inclusive of each other in view of comparing their variables in their respective claims; they are overlapped with each other. This difference can not impart patentability because the reorganizing limitations of the claims are an obvious step. Therefore, it would have been obvious to the skilled artisan to be motivated to reorganize the claimed limitations in order to emphasize the particular aspects of the current invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates and hydrates of the claimed compounds. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. "The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. In the present case the important factors leading to a conclusion of undue experimentation are the absence of any working example of a formed solvate, the lack of predictability in the art, and the broad scope of the claims.

c) There is no working example of any hydrate or solvate formed. The claims are drawn to solvates, yet the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here. There is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

g) The state of the art is that is not predictable whether solvates will form or what their composition will be. In the language of the physical chemist, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). West, Anthony R., "Solid State Chemistry and its Applications, Wiley, New York, 1988, pages 358 & 365. The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometry of the formed solvate, i.e. if one, two, or a half a molecule of solvent

added per molecule of host. In the same paragraph on page 365 West (Solid State Chemistry) explains that it is possible to make meta-stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent or even the moisture of the air that might change the stable region of the solvate.

h) The breadth of the claims includes all of the hundreds of thousands of compounds of claimed compound as well as the presently unknown list of solvents embraced by the term "solvate". Thus, the scope is broad.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claims 1, 13, and 14, the terms "contains" and "containing" are recited. These expressions are vague and indefinite because the terms "contains" and "containing" would mean that there were some additional components present in addition to the ones recited. The claims do not specify what other additional components are. Therefore, an appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

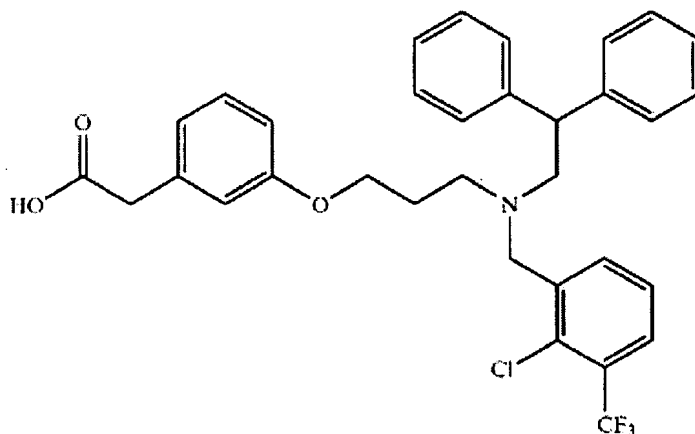
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-12, 14, 16, 19, 21, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Collins et al (US 2004/0072868).

Collins et al discloses the following compound as shown below (see col. 18, ex. 16):

EXAMPLE 16

[0315] 2-(3-{3-[[2-Chloro-3-(trifluoromethyl)benzyl](2,2-diphenylethyl)amino]propoxy}-phenyl)acetic Acid



This is identical with the claims.

Claims 1-7, 9-12,14,16,19, 21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins et al (J. Med. Chem. 2002, 45, 1963-1966).

Collins et al discloses the following compound as shown below (see page 1964, Table 1):

Table 1. LXR Activity of Tertiary Amines^a


| compd | n | X | R | EC ₅₀ (nM) | RE | EC ₅₀ (nM) | RE |
|-------|---|---|-------------------------------------------|--------------------------|-----|--------------------------|-----|
| 12 | 1 | O | metnyl 2-chloro-3-trifluoro- methyl | 125 ± 20 | 1.0 | 190 ± 30 | 1.7 |

This is identical with the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Taylor Victor Oh, MSD,LAC
Primary Examiner
Art Unit : 1625

